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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|------------------|----------------------|-------------------------|------------------|
| 09/845,597 | 04/30/2001 | Antoni P. Tomsia | IB-1627 | 3236 |
| 8076 | 7590 02/28/2003 | | | |
| | E BERKELEY NATIO | EXAMINER | | |
| ONE CYCLOTRON ROAD, MAIL STOP 90B UNIVERSITY OF CALIFORNIA | | | SPERTY, ARDEN B | |
| BERKELEY, | CA 94720 | | ART UNIT | PAPER NUMBER |
| | | | 1775 | |
| | | | DATE MAILED: 02/28/2003 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

| | Applicati n No. | | Ω | |
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| | i | Applicant(s) | 100 | |
| Office Action Summary | 09/845,597 Examiner | TOMSIA ET AL. | | |
| | 1. | Art Unit | | |
| The MAILING DATE of this communication app | pears on the c ver sheet wi | 1775 | | |
| A SHORTENED STATUTORY STATU | | ar the correspondence add | ress | |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, - Any reply received by the Office later than three months after the mailing - status Status | 36(a). In no event, however, may a re | ply be timely filed | munication. | |
| 1) Responsive to communication(s) filed on <u>24 D</u> | 1000mh 0000 | | | |
| | | | | |
| 3) Since this application is in condition (| s action is non-final. | | | |
| Since this application is in condition for allower closed in accordance with the practice under EDisposition of Claims | nce except for formal matte | ers, prosecution as to the n | nerits is | |
| | Paris Garage, 1935 C.D. | 11, 453 O.G. 213. | | |
| 4)⊠ Claim(s) <u>1-20</u> is/are pending in the application. | | | | |
| 4a) Of the above claim(s) is/are withdrawn | n from consideration. | | | |
| is/are allowed. | | | | |
| 6)⊠ Claim(s) <u>1-20</u> is/are rejected. | | | | |
| 7) Claim(s) is/are objected to. | | | | |
| 8) Claim(s) are subject to restriction and/or e Application Papers | election requirement | | | |
| • | - 40011(. | | | |
| 9) The specification is objected to by the Examiner. | | | | |
| 10) The drawing(s) filed on is/are: a) accepted | d or b) objected to by the | Examiner | | |
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| | all langroyed by liv | Oproved by the Examiner | | |
| | | in the by the Examiner. | | |
| 12) The oath or declaration is objected to by the Exami | iner. | | | |
| riority under 35 U.S.C. §§ 119 and 120 | | | | |
| 13) Acknowledgment is made of a claim for foreign pri a) All b) Some * c) None of: | ority under 35 U.S.C. & 11 | 9(a)-(d) or (f) | | |
| N = SILI None of. | | o(a)-(a) or (i). | | |
| 1. Certified copies of the priority documents ha | ve been received | | | |
| Gertified copies of the priority documents have been seed to the | | | | |
| application from the Late priority d | locuments have been rece | ivad in this turn. | | |
| | | ved. | | |
| 4) Acknowledgment is made of a claim for domestic price a) The translation of the foreign language provision | ority under 35 U.S.C. § 119 | e) (to a provisional applic | ation). | |
| Acknowledgment is made of a claim for domestic action | nal application has been re | eceived. | | |
| chment(s) | only under 35 U.S.C. §§ 12 | 20 and/or 121. | | |
| Notice of References Cited (PTO-892) | _ | | | |
| Median (P | A. [7] | | | |
| Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8. | 4) Interview Summa | ry (PTO-413) Paper No(s) Patent Application (PTO-152) | | |

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FINAL REJECTION

Priority

1. Applicant's claim for priority to Provisional Application 60/201,556 is denied. The provisional application does not provide a specification disclosing the claimed invention, therefore there is no support for the claimed invention.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-19 are rejected under 35 U.S.C. 102(b) as being anticipated by the Bioceramics: Materials and Applications III article titled "Glass-hydroxyapatite coatings on titanium-based implants" published in December 1999.

Regarding claim 1, the Bioceramics article teaches a multilayer article comprising a titanium alloy metal substrate (see abstract), a first layer having an inner and outer surface and comprising a glass/hydroxyapatite (HA) admixture having the claimed composition (see abstract, Table I and bottom of page 16).

Regarding claim 2, the reference discloses the article of claim 1 wherein there is a higher concentration of HA particles nearer the outer surface than the inner surface (page 17, lines 25-27; page 19, lines 3-8).

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Regarding claim 3, the reference discloses the article of claim 1 having multiple layers (intermediate layers) (page 19, lines 5-8) comprising a glass composition as defined in claim 1 (see Table I).

Regarding claim 4, the first layer has a HA concentration of 40% (page 19, lines 5-8).

Regarding claims 5-6, the reference discloses the articles of claims 3 or 4 having a first intermediate layer having a HA concentration of 0%, a second intermediate layer having a HA concentration of 20%, and a first layer having a HA concentration of 40% (page 19, lines 5-8).

Regarding claim 7, the glasses may be chosen from any of those in Table I of the reference, therefore the limitations of the claim are met.

Regarding claim 8, the reference discloses the articles of claims 1 or 7 wherein the substrate is Ti6Al4V (see abstract).

Regarding claims 9-12, Table I of the reference discloses the claimed glass compositions on a substrate of Ti6Al4V and HA concentrations meeting the claim limitations.

Regarding claims 13-17 and 19, the reference discloses a multilayer article comprising a Ti6Al4V substrate (see abstract) having a first layer and n intermediate layers, the layers comprising the claimed glass composition (see Table I) and wherein the first layer has the highest HA concentration and each subsequent layer has a gradually decreasing HA concentration (page 19, first paragraph), all concentrations being within 1.0 to 50 %.

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Regarding claim 18, the reference teaches the article of claim 13 having the claimed glass composition and a first layer comprising 50% glass and 50% HA (page 16, lines 32-33).

Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over the Bioceramics: Materials and Applications III article titled "Glass-hydroxyapatite coatings on titanium-based implants" published in December 1999.

Regarding claim 20, the reference discloses a multilayer article comprising a Ti6Al4V substrate (see abstract) having a first layer and 2 intermediate layers, the layers comprising the claimed glass composition (see Table I) and wherein the first layer has the highest HA concentration and each subsequent layer has a gradually decreasing HA concentration (page 19, first paragraph). Although the reference does not specifically disclose the gradation in SiO₂ concentration, such a gradient is inherently formed by variations in glass compositions. Absent a showing of unexpected results with a varying SiO₂ concentration no patentable distinction is seen between the instant claim and that of the prior art.

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Response to Arguments

6. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new grounds of rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arden B. Sperty whose telephone number is 703-305-3143. The examiner can normally be reached on M-R, 08:00-16:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Jones can be reached on 703-308-3822. The fax phone numbers for

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the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

abs

February 24, 2003

SUPERVISORY PATENT EXAMINER